

G4

Quality System

Regulation Coverage

## QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G4 (Activity 1)	Provide broad and adequate coverage of the Quality System Regulation when conducting a comprehensive Quality System inspection.	
Term <sup>1</sup>	Type of activity (test or analysis)	Parameter(s) to be measured
Short	Analysis	QSIT Inspectional Objectives and narrative "linkages" described within the "QSIT Inspection Handbook"
<b>Scope and nature of the process to be followed.<sup>2</sup></b>	<p>Compare QSIT Inspectional Objectives and "linkages" with the requirements of the QS Regulation. Determine whether the QSIT provides for the inspection of the requirements of the QS Regulation either directly through Inspectional Objectives or indirectly through "linkages".</p> <p>This comparison will be accomplished using CSO Chris Nelson's (FDA, CDRH GMP Expert) model "SUBSYSTEM PURPOSE, TOOLS AND RELATED SECTIONS OF THE QUALITY SYSTEM REGULATION" as the tool for comparison. CSO Nelson's model will be compared to the requirements of the QS Regulation to determine if any "gaps" exist between CSO Nelson's model and the regulation. The QSIT Inspectional Objectives and "linkages" will be compared against CSO Nelson's model to determine if any "gaps" exist between the inspectional requirements of QSIT and the regulatory requirements of the QS Regulation (via CSO Nelson's model). CSO Nelson's model was selected as an intermediary document because it has already aligned the requirements of the QS Regulation with the concept of a quality system consisting of "seven subsystems".</p> <p>Overall responsibility for this activity: R. Ruff (HFR-CE350)</p>	
<b>Acceptance criteria (if known)</b>	QSIT Inspectional Objectives and "linkages" provide for the inspection of the requirements of the QS Regulation.	
<b>Extent to which the activity measures/confirms how well the goal/outcome has been met.<sup>3</sup> (strengths and weaknesses of this validation activity)</b>	This activity will provide direct and objective evidence that while fulfilling the requirements necessary to meet QSIT Inspectional Objectives, the requirements of the QS Regulation are inspected. Since we are comparing the requirements of QSIT to the QS Regulation requirements, there are no apparent weaknesses in this activity.	
<b>Reason(s) why the activity represents one of the best approaches to measuring the accomplishment of the goal/outcome.</b>	This pre-deployment activity will demonstrate that the QSIT provides for the inspection of the requirements of the QS Regulation.	

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<sup>1</sup> Short term = pre-deployment event, long-term = post-deployment event

<sup>2</sup> Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

<sup>3</sup> Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

## QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G4	Provide broad and adequate coverage of the Quality System Regulation when conducting a comprehensive Quality System inspection.	
Activity #	Type of activity (test or analysis)	Parameter(s) to be measured
1	Analysis	QSIT Inspectional Objectives and narrative "linkages" described within the "QSIT Inspection Handbook"
Acceptance Criteria	QSIT Inspectional Objectives and "linkages" provide for the inspection of the requirements of the QS Regulation.	
Summary of Results	<p>A comparison of the requirements of the Quality System Regulation (21 CFR Part 820) with CSO Chris Nelson's model "SUBSYSTEM PURPOSE, TOOLS AND RELATED SECTIONS OF THE QUALITY SYSTEM REGULATION" appears within Attachment 1. Also contained within Attachment 1 is a comparison of the QSIT Handbook Inspectional Objectives (including tasks associated with the accomplishment of these objectives as described within the narrative discussion of each objective) and linkages.</p> <p>Concerning CSO Nelson's model, two sections of the QS Regulation were not captured within the model ("820.1 Scope" and "820.3 Definitions").</p> <p>Concerning the QSIT Handbook, twelve sections of the QS Regulation were not directly captured for review via Inspectional Objectives or narrative discussions or indirectly through linkages. The sections were: "820.1 Scope", "820.3 Definitions", "820.60 Identification", "820.65 Traceability", "820.70(f) Buildings" (all other requirements of 820.70 captured), "820.86 Acceptance Status", "820.120 Device Labeling" (requirements other than Design Control), "820.140 Handling", "820.150 Storage", "820.160 Distribution", "820.170 Installation", "820.180 Records" (other than 820.180(c)).</p> <p>On 3/3/99, a meeting was held between CSO Robert Ruff, NWJ-DO (sub-team leader of "QSIT Handbook Content" sub-team) and CSO Corinne Tylka, CDRH OC (acting sub-team leader in CSO Ruff's absence) to discuss and agree upon the changes required to address the deficiencies of the QSIT Handbook. The "Comments" column of Attachment 1 contains descriptions of the corrective actions (changes to the QSIT Handbook) necessary to address the deficiencies. CSO Tylka was assigned the responsibility for coordinating the change activities with CDRH OC support staff. CSO Tylka and/or CSO Ruff will verify that the appropriate changes have been implemented and a final QSIT Handbook will be available NLT 4/1/99.</p> <p>Activity references: (1) 21 CFR Part 820 (2) CSO Nelson's "SUBSYSTEM PURPOSE, TOOLS AND RELATED SECTIONS OF THE QUALITY SYSTEM REGULATION" (3) "QSIT INSPECTION HANDBOOK October 1998 Draft"</p>	
Conclusion	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments	21 CFR Part 820, Sections "820.1 Scope" and "820.3 Definitions" are captured within an Investigator's general training. Therefore, these sections are not specifically captured within the text or linkages of the QSIT Handbook.	
Activity Champion(s)		Robert G. Ruff, CSO (HFR-CE350)

Q5IT Validation Item G4: Provide broad and adequate coverage of the Quality system Regulation when conducting a comprehensive Quality system inspection.  
Key: MC = Management Controls DC = Design Controls CAPA = Corrective and Preventive Actions P&PC = Production and Process Controls SPC = Sterilization Process Controls  
)1, O2... = Objective 1, Objective 2, etc. L = Linkage FC = Flow Chart Examples: 820.20(a) Quality Policy is covered by QSIT "MCO1" and "MCO2" = Management Control  
)bjectives 1 and 2; If the requirement is covered by QSIT "P&PCO2L", it is covered by a "Linkage" from P&PC Objective 2. G4 Activity 1 Attach. 1 3 pp.

Quality System Regulation	CSO Nelson's Alignment	QSIT Coverage	Comments
820.1(a)-(e) Scope	No	No	Training issue
820.3 (a) - (aa) Definitions	No	No	Training issue
820.5 Quality System	Yes	Yes ("Getting Started")	Confirmation is an ultimate goal of QSIT
820.20 Management Respon.	Section Title	Section Title	
820.20(a) Quality Policy	Yes	Yes (MCO1, MCO2)	
820.20(b) Organization	Yes	Yes (MCO3, MCO4)	
820.20(b)(1) Resp. and Auth.	Yes	Yes (MCO3)	
820.20(b)(2) Resources	Yes	Yes (MCO3)	
820.20(b)(3) Management Rep.	Yes	Yes ("Getting Started", MCO4)	
820.20(c) Management Review	Yes (Mgt and Fac. & Equip.)	Yes (MCO1, MCO5, CAPAO10)	
820.20(d) Quality planning	Yes	Yes (MCO1)	
820.20(e) Quality system proc's	Yes	Yes (MCO1)	
820.22 Quality Audit	Yes	Yes (MCO6)	
820.25 Personnel	Section Title	Section Title	
820.25(a) General	Yes	Yes (P&PCO6L, SPCO5L)	
820.25(b) Training	Yes (Mgt and P&PC)	Yes (P&PCO6, SPCO5)	
820.30 Design Control	Section Title	Section Title	
820.30(a) General	Yes	Yes (DCO1)	
820.30(b) Design and Dev. Plan.	Yes	Yes (DCO3)	
820.30(c) Input	Yes	Yes (DCO2, DCO4)	
820.30(d) Output	Yes	Yes (DCO2, DCO5)	
820.30(e) Review	Yes	Yes (DCO2, DCO14)	
820.30(f) Verification	Yes	Yes (DCO2, DCO6, DCO7)	
820.30(g) Validation	Yes	Yes (DCO2, DCO6, DCO8 - DCO12)	
820.30(h) Transfer	Yes	Yes (DCO2, DCO15)	
820.30(i) Changes	Yes (Doc. & Change Control)	Yes (DCO2, DCO13)	
820.30(j) DHF	Yes (Doc. & Change Control)	Yes (DCO2)	
820.40 Document Controls	Yes	Yes (P&PCO2L, SPCO2L)	
820.40(a) Approval and Distrib.	Yes	Yes (P&PCO2L, SPCO2L)	
820.40(b) Changes	Yes	Yes (P&PCO2L, SPCO2L)	Add 820.50 cite to P&PC and SPC FC Box (2)
820.50 Purchasing Controls	Yes	Yes (DCO5L, P&PCO2, SPCO2)	Covered by comment to 820.50 above
820.50(a) Evaluation of Suppliers	Yes	Yes (DCO5L, P&PCO2, SPCO2)	Covered by comment to 820.50 above
820.50(b) Purchasing data	Yes	Yes (DCO5L, P&PCO2, SPCO2)	Add as linkage to P&PCO2 & SPCO2
820.60 Identification	Yes	No	Add as linkage to P&PCO2 & SPCO2
820.65 Traceability	Yes	No (indirectly through review of DHR)	Add as linkage to P&PCO2 & SPCO2
820.70 P&PC	Section Title	Section Title	
820.70(a) General	Yes	Yes (P&PCO2, SPCO2)	Add 820.70(b) cite to DC FC Box (13)
820.70(b) Changes	Yes (Doc. & Change Control)	Yes (DCO13)	Add 820.70(c) cite to P&PC and SPC FC Box (2)
820.70(c) Envir. Control	Yes (Fac. & Equip.)	Yes (P&PCO2, SPCO2)	Add 820.25 and 870.70(d) cites to P&PC FC Box (6) and SPC FC Box (5)
820.70(d) Personnel	Yes	Yes (P&PCO6, SPCO5)	Add 820.70(e) cite to P&PC and SPC FC Box (2)
820.70(e) Contamination	Yes (Fac. & Equip.)	Yes (P&PCO2, SPCO2)	Add new para. to pp. 85 & 98, just prior to "Verify that the control..." para. To state: "Verify that the building is of suitable design and contains sufficient space to perform necessary operations." Add 820.70(f) cite to P&PC and SPC FC Box (2)
820.70(f) Buildings	Yes	No	Add 820.70(g) cite to P&PC and SPC FC Box (2)
820.70(g) Equipment	Yes	Yes (P&PCO2, SPCO2)	Add 820.70(h) cite to P&PC and SPC FC Box (2)
820.70(h) Manufact. Mat'l	Yes	Yes (P&PCO2, SPCO2)	
820.70(i) Automated processes	Yes	Yes (P&PCO5, SPCO4)	
820.70(j) Fac. & Test Equip.	Section Title	Section Title	

**SIT Validation Item G4: Provide broad and adequate coverage of the Quality system Regulation when conducting a comprehensive Quality system inspection.**

Key: MC = Management Controls DC = Design Controls CAPA = Corrective and Preventive Actions P&PC = Production and Process Controls SPC = Sterilization Process Controls  
 1, 02... = Objective 1, Objective 2, etc. L = Linkage FC = Flow Chart Examples: 820.20(a) Quality Policy is covered by QSIT "MCO1" and "MCO2" = Management Control objectives 1 and 2; If the requirement is covered by QSIT "P&PCO2L", it is covered by a "Linkage" from P&PC Objective 2. G4 Activity 1 Attach. 1 3 pp.

Quality System Regulation		CSO Nelson's Alignment		QSIT Coverage		Comments
820.75 Process validation	Section Title	Section Title	Section Title	Section Title	Section Title	
820.75(a) validation procedures	Yes	Yes	Yes (P&PCO4)	Yes (P&PCO4)	Yes (P&PCO4)	Add 820.75(a) cite to P&PC FC Box (4) and SPC FC Box (1) add statement re: procedures to SPCO1 Narrative p. 93 para. 1 "Validation studies (according to established procedures) are required..." and para. 3, sentence 2, "...must include a review of the established validation procedures and verification..."
820.75(b) monitoring and control	Yes	Yes	Yes (P&PCO2, P&PCO3, P&PCO6, SPCO2, SPCO3, SPCO5)	Yes (P&PCO2, P&PCO3, SPCO2, SPCO5)	Yes (P&PCO2, P&PCO3, SPCO2, SPCO5)	Add 820.75(c) cite to P&PC FC Box (4) and SPC FC Box (1)
820.75(c) changes, deviations	Yes	Yes	Yes (DCO13, P&PCO2, SPCO2)	Yes (DCO13, P&PCO2, SPCO2)	Yes (DCO13, P&PCO2, SPCO2)	Add 820.80 cite to P&PC and SPC FC Box (2)
820.80 Acceptance Activities	Section Title	Section Title	Section Title	Section Title	Section Title	Covered by comment to 820.80(a) above
820.80(a) General	Yes	Yes	Yes (P&PCO2, SPCO2)	Yes (P&PCO2, SPCO2)	Yes (P&PCO2, SPCO2)	Covered by comment to 820.80(a) above
820.80(b) Receiving	Yes (Mat'l Control)	Yes	Yes (P&PCO2, SPCO2)	Yes (P&PCO2, SPCO2)	Yes (P&PCO2, SPCO2)	Covered by comment to 820.80(a) above
820.80(c) In-process	Yes	Yes	Yes (P&PCO2, SPCO2)	Yes (P&PCO2, SPCO2)	Yes (P&PCO2, SPCO2)	Covered by comment to 820.80(a) above
820.80(d) Final	Yes	Yes	Yes (P&PCO2, SPCO2)	Yes (P&PCO2, SPCO2)	Yes (P&PCO2, SPCO2)	Covered by comment to 820.80(a) above
820.80(e) Acc. Records	Yes	Yes	Yes (P&PCO2, SPCO2)	Yes (P&PCO2, SPCO2)	Yes (P&PCO2, SPCO2)	Add linkage to P&PCO2 and SPCO2
820.86 Acc. Status	Yes	Yes	No	No	No	
820.90 Nonconforming product	Section Title	Section Title	Section Title	Section Title	Section Title	
820.90(a) Control	Yes	Yes	Yes (P&PCO3, SPCO3)	Yes (P&PCO3, SPCO3)	Yes (P&PCO3, SPCO3)	
820.90(b) Review and Disposit.	Yes	Yes	Yes (P&PCO3, SPCO3)	Yes (P&PCO3, SPCO3)	Yes (P&PCO3, SPCO3)	
820.100 CAPA	Section Title	Section Title	Section Title	Section Title	Section Title	
820.100(a) CAPA Procedures	Yes	Yes	Yes (DCO5L, CAPAO1 - CAPAO10)	Yes (DCO5L, CAPAO1 - CAPAO10)	Yes (DCO5L, CAPAO1 - CAPAO10)	
820.100(b) CAPA documentation	Yes	Yes	Yes (CAPAO9)	Yes (CAPAO9)	Yes (CAPAO9)	
820.120 Device Labeling	Yes	Yes	Yes (DCO5L)	Yes (DCO5L)	Yes (DCO5L)	p. 83 "NOTE", make the existing note "1." Add a note to state: "2. If Device Labeling is the process chosen, include in your inspection coverage of the requirements of "820.120 Device Labeling".
820.120(a) Label integrity	Yes	Yes	No	No	No	Covered by comment to 820.120 above
820.120(b) Labeling inspection	Yes	Yes	No	No	No	Covered by comment to 820.120 above
820.120(c) Labeling storage	Yes	Yes	No	No	No	Covered by comment to 820.120 above
820.120(d) Labeling operations	Yes	Yes	No	No	No	Covered by comment to 820.120 above
820.120(e) Control number	Yes	Yes	Yes (DCO1 - DCO15)	Yes (DCO1 - DCO15)	Yes (DCO1 - DCO15)	Add linkage to P&PCO2, SPCO2
820.130 Device packaging	Yes	Yes	No	No	No	Add linkage to P&PCO2, SPCO2
820.140 Handling	Yes	Yes	Section Title	Section Title	Section Title	
820.150 Storage	Section Title	Section Title	Section Title	Section Title	Section Title	
820.150(a) Proc. control	Yes	Yes	No	No	No	Add 820.150 linkage to P&PCO2, SPCO2
820.150(b) Proc. Rec. & dispatch	Yes	Yes	No	No	No	Covered by comment to 820.150(a) above
820.160 Distribution	Section Title	Section Title	Section Title	Section Title	Section Title	
820.160(a) Procedures	Yes	Yes	No	No	No	Add 820.160 linkage to P&PCO2, SPCO2
820.160(b) Records	Yes	Yes	No	No	No	Covered by comment to 820.160(a) above
820.170 Installation	Section Title	Section Title	Section Title	Section Title	Section Title	
820.170(a) instruct's & proc.s	Yes	Yes	No	No	No	Add as "linkages" following narrative of CAPAO4 "Important linkages for this activity include 820.80 Acceptance Activities, 820.90 Nonconforming Product, 820.170 Installation, 820.198 Complaint Files and 820.200 Servicing."
820.170(b) install. & records	Yes	Yes	No	No	No	Covered by comment to 820.170(a) above
820.180 Records	Yes	Yes	No	No	No	Add 820.180 linkage to P&PCO2, SPCO2
820.180(a) Confidentiality	Yes	Yes	No	No	No	Covered by comment to 820.180 above
820.180(b) Retention	Yes	Yes	No	No	No	Covered by comment to 820.180 above
820.180(c) Exceptions	Yes	Yes	Yes (MCO5, CAPAO2)	Yes (MCO5, CAPAO2)	Yes (MCO5, CAPAO2)	
820.181 DMR	Yes	Yes	Yes (DCO15, P&PCO2, SPCO2)	Yes (DCO15, P&PCO2, SPCO2)	Yes (DCO15, P&PCO2, SPCO2)	
820.181 DMR	Yes	Yes	Yes (DCO15, P&PCO2, SPCO2)	Yes (DCO15, P&PCO2, SPCO2)	Yes (DCO15, P&PCO2, SPCO2)	

Validation Item G4: Provide broad and adequate coverage of the Quality system Regulation when conducting a comprehensive Quality system inspection. Key: MC = Management Controls DC = Design Controls CAPA = Corrective and Preventive Actions P&PC = Production and Process Controls SPC = Sterilization Process Controls 1, O2... = Objective 1, Objective 2, etc. L = Linkage FC = Flow Chart Examples: 820.20(a) Quality Policy is covered by QSIT "MCO1" and "MCO2" = Management Control Objectives 1 and 2; If the requirement is covered by QSIT "P&PCO2L", it is covered by a "Linkage" from P&PC Objective 2. G4 Activity 1 Attach. 1 3 pp.

Quality System Regulation	CSO Nelson's Alignment	QSIT Coverage	Comments
820.181(c) QA procedures	Yes	Yes (DCO15, P&PCO2, SPCO2)	
820.181(d) pkg. & labeling spec.s	Yes	Yes (DCO15, P&PCO2, SPCO2)	
820.181(e) Install., Maint. Serv.	Yes	Yes (DCO15, P&PCO2L, SPCO2L)	
820.184 DHR	Yes	Yes (P&PCO2, SPCO2)	
820.184(a) dates of manuf.	Yes	Yes (P&PCO2L, SPCO2L)	
820.184(b) quantity manuf.	Yes	Yes (P&PCO2L, SPCO2L)	
820.184(c) quantity released dist.	Yes	Yes (P&PCO2, SPCO2)	
820.184(d) acceptance records	Yes	Yes (P&PCO2L, SPCO2L)	
820.184(e) prim. ID label(ing)	Yes	Yes (P&PCO2L, SPCO2L)	
820.184(f) ID, Control Num.	Yes	Yes (P&PCO2, P&PCO6, SPCO2, SPCO5)	
820.186 QSR	Yes	Section Title	
820.198 Complaint Files	Section Title	Yes (CAPAO1)	
820.198(a) Compl. Procedures	Yes	Yes (CAPAO1)	Covered by comment to 820.170(a) above
820.198(b) Compl. Rev. & Eval.	Yes	Yes (CAPAO1)	Covered by comment to 820.170(a) above
820.198(c) Compl. Invest.	Yes	Yes (CAPAO1)	Covered by comment to 820.170(a) above
820.198(d) 803, 804 Compl.s	Yes	Yes (CAPAO1)	Covered by comment to 820.170(a) above
820.198(e) Invest. Record	Yes	Yes (CAPAO1)	Covered by comment to 820.170(a) above
820.198(f) rec. reas. access.	Yes	Yes (CAPAO1)	Covered by comment to 820.170(a) above
820.198(g) rec. access. in US	Yes	Yes (CAPAO1)	Covered by comment to 820.170(a) above
820.200 Servicing	Section Title	Section Title	
820.200(a) instruct.s and proc.s	Yes	Yes (CAPAO1)	Covered by comment to 820.170(a) above
820.200(b) Ser. Rpt. Analysis	Yes	Yes (CAPAO1)	Covered by comment to 820.170(a) above
820.200(c) 803, 804 Ser. Rpts.	Yes	Yes (CAPAO1)	Covered by comment to 820.170(a) above
820.200(d) Ser. Rpt. Document.	Yes	Yes (CAPAO2, CAPAO3, CAPAO5, CAPAO6, P&PCO2, SPCO2)	
820.250 Statistical Techniques	Yes	Yes (CAPAO2, CAPAO3, CAPAO5, CAPAO6, P&PCO2, SPCO2)	
820.250(a) Proc.s to ID techn.s	Yes	Yes (CAPAO2, CAPAO3, CAPAO5, CAPAO6, P&PCO2, SPCO2)	
820.250(b) Proc.s for sampling	Yes	Yes (P&PCO2, SPCO2)	

## QSIT VALIDATION WORKSHEET

<b>Item #</b>	<b>Goal/Outcome</b>	
G4	Quality System Regulation Coverage	
<b>Term<sup>1</sup></b>	<b>Type of activity (test or analysis)</b>	<b>Parameter(s) to be measured</b>
Short Term	Analysis	Evaluate whether the instructions in the QSIT Handbook adequately address the requirements of the quality system regulation (QSR), and whether the inspection strategy assesses the quality system.
<b>Scope and nature of the process to be followed.<sup>2</sup></b>	A group of industry representatives, regulatory consultants, and trade association executives will compare the quality system regulation with the QSIT Handbook. They will determine if the QSIT Handbook covers the key elements of the QSR. They will document their findings in a written report. The industry group consists of Don Barth, Hewlett-Packard; Rich Farb, Baxter Healthcare; Ron Johnson, Quintiles BRI; Ken Kopesky, Medtronic, Inc.; David Link, Expertech; Susan Moritz, Boston Scientific Corporation; Nancy Singer, HIMA; Robert Turocy, Picker International; and Bob Wurzel, Becton Dickinson and Company. Attachment I contains biographical information about the industry representatives. This activity is to be completed by February 25, 1999.	
<b>Acceptance criteria (if known)</b>	Consensus among the group members.	
<b>Extent to which the activity measures/confirms how well the goal/outcome has been met.<sup>3</sup> (strengths and weaknesses of this validation activity)</b>		Subjective measurements by qualified experts and professionals.
<b>Reason(s) why the activity represents one of the best approaches to measuring the accomplishment of the goal/outcome.</b>		Two expert parties (an industry group and an FDA group) will perform this analysis independently. If the two analyses are reasonably congruent, that should provide a high degree of confidence in the findings.

<sup>1</sup> Short term = pre-deployment event, long-term = post-deployment event

<sup>2</sup> Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

<sup>3</sup> Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

## BIOGRAPHICAL SKETCHES

**Donald J. Barth** is the regulatory staff manager for the Medical Products Group (MPG) of Hewlett Packard (HP). He is responsible as a senior representative and negotiator for all of HP's Washington-based medical device regulatory initiatives. He helps to influence the programs and policies that support compliance with medical device laws in all of the countries in which MPG conducts business, as well as the group-wide implementation of ISO 9000 compliance programs. Mr. Barth began his career as a design engineer specializing in electronic hardware and firmware for airborne computer systems. He joined Hewlett Packard in 1973 as a marketing support engineer. Subsequently, he held several positions in manufacturing related to systems integration and testing. He then joined the R&D group as systems integration manager of several different computer-based products, with a particular focus on tools and methodologies to ensure high quality products. He earned a master's in electrical engineering at Columbia University, and a bachelor's in electrical engineering at New York University.

**Richard Farb** is corporate director of regulatory compliance for Baxter International. Mr. Farb started his career with Baxter in 1965 in biomedical engineering research and development. He has experience in various positions and divisions of Baxter and has been vice president of regulatory affairs and quality assurance for two divisions. His current responsibilities include monitoring new regulatory requirements and worldwide harmonization efforts for regulatory requirements. He is the convener of ISO TC210 WG3, which has ISO jurisdiction for medical device nomenclature and symbols for use in labeling for medical devices. Mr. Farb has a bachelor's degree with concentrations in physiology and chemistry from Southern Illinois University and a master's degree from the University of Chicago.

**Ronald M. Johnson** is vice president for Quintiles Consulting global operations, responsible for management of the division's West Coast operations. Mr. Johnson directs and oversees the planning, development, and implementation of the Quality System Regulation including design control provisions, adverse event reporting requirements, drug and biologics GMPs, GCPs, and ISO 9000. He was with the FDA for thirty years, serving a wide array of positions in both headquarters and the field organization. During his last twelve years, he served as District Director and Regional Director in FDA's field force and as Director, Office of Compliance, Center for Devices and Radiological Health. In these positions Mr. Johnson was directly responsible for many of the agency's contemporary enforcement and compliance initiatives, particularly in the medical device area. As Director of FDA's Pacific Region, he initiated an industry outreach program to facilitate interaction and collaboration between FDA and the regulated industry.

**Ken Kopesky** is the director of corporate compliance and audit for Medtronic, Inc. His responsibilities are managing the overall compliance of Medtronic businesses regarding quality, regulatory, and clinical activities. He has been with Medtronic for 27 years and has held management positions in quality assurance, return product analysis, service, operations, and manufacturing development. He also is a member of GHTF Study Group 2 and serves on a number of association committees.

**David M. Link** has more than 35 years of experience in the medical device industry. While at Hewlett Packard Company, he served in research and development, manufacturing, and marketing functions. From 1970 to 1980, he managed the medical device program at FDA. As

the first director of the Bureau from 1974 to 1980, he was instrumental in establishing the regulatory philosophy, which permitted growth and encouraged innovation in the U.S. medical device industry. Mr. Link received his B.S. in physics from the Massachusetts Institute of Technology, his M.S. in nuclear physics from the University of Illinois, and his M.B.A. from the Harvard Graduate School of Business Administration.

**Susan Moritz** is the manager of corporate compliance for Boston Scientific Corporation, a multinational manufacturer and distributor of medical devices. Ms. Moritz has world-wide responsibility for the assessments of the quality systems utilized by Boston Scientific and its various divisions. Her group develops and conducts audit programs that assess the degree and extent of compliance to applicable regulations and/or practices such as the Quality System Regulation, ISO 9001, ISO 13485 and the Medical Device Directives. In this role, Ms. Moritz coordinated and conducted training for BSC personnel world wide on the design control requirements of the Quality System Regulation. Ms. Moritz has been working in the quality arena for the past 11 years and holds a bachelor's degree in biology and a master's degree in business administration.

**Nancy Singer** is special counsel at HIMA. In this capacity she serves as counsel for FDA enforcement matters. Previously, she was executive director of the Food and Drug Law Institute. Her food and drug career began as an attorney at the United States Department of Justice where she did litigation for the Food and Drug Administration. Subsequently she was a partner at the law firm of Kleinfeld, Kaplan and Becker. Ms. Singer received her B.S. from Cornell University, and her J.D. and LL.M. degrees from New York University Law School.

**Robert L. Turocy** is the corporate regulatory affairs & compliance manager for Picker International, Inc. and has more than 28 years of experience in the medical device imaging industry. During the first ten years at Picker, Mr. Turocy worked in the engineering department as a mechanical designer and a product safety specialist. The last eighteen years, he has an extensive background and experience in the regulatory requirements for medical imaging devices. Mr. Turocy is a Picker representative to NEMA Committees (Legislative & Regulatory, GMP, International, and a Chairman of the X-Ray Technical & Government Relations). He has served as a member of the FDA Technical Electronic Product Radiation Safety Standards Advisory Committee. He is a member of RAPS, AAMI, and ASQ wherein he is a Certified Quality Auditor. He is a member of IEC Working Group 15 and an alternate to other IEC Working Groups.

**Robert D. Wurzel** is vice president, regulatory and quality affairs at Becton Dickinson and Company in Franklin Lakes, New Jersey. Mr. Wurzel joined Becton Dickinson in 1989 and was elected a Corporate Officer in October 1994. Since 1970, Mr. Wurzel has held senior quality and regulatory affairs management positions in several international healthcare companies. Prior to his industry experience, Mr. Wurzel spent 18 years in public health and clinical laboratories. Mr. Wurzel presently is the U.S. industry representative on Working Group 4 of the Medical Device Global Harmonization Task Force. This Working Group is pursuing the harmonization of regulatory auditing worldwide. He is a member of the ANSI and AAMI Boards of Directors and was a 1997 Malcolm Baldrige National Quality Award Examiner. Mr. Wurzel holds an M.B.A. from Pepperdine University and has an undergraduate degree from Bowling Green State University (Ohio).

## QSIT VALIDATION ACTIVITY REPORT

<b>Item #</b>	<b>Goal/Outcome</b>	
G4	Quality System Regulation Coverage	
<b>Activity #</b>	<b>Type of activity</b> (test or analysis)	<b>Parameter(s)</b> to be measured
2	Analysis	Evaluate whether the instructions in the QSIT Handbook adequately address the requirements of the quality system regulation (QSR) and whether the inspection strategy adequately assesses the quality system
<b>Acceptance Criteria</b>	There was consensus among the group members: Dön Barth, Hewlett-Packard; Rich Farb, Baxter Healthcare; Ron Johnson, Quintiles BRI; Ken Kopesky, Medtronic, Inc.; David Link, Expertech; Susan Moritz, Boston Scientific Corporation; Nancy Singer, HIMA; Robert Turocy, Picker International; and Bob Wurzel, Becton Dickinson and Company.	
<b>Summary of Results</b>	The instructions in the QSIT Handbook expressly cover the four major subsystems of the QSR and can be linked to the remaining provisions in the QSR as indicated in the attached chart. Each firm's method of applying the various provisions of the QSR will depend on its products and operations. Ultimately, the depth (sampling tables) and breadth (linkages) of the inspection will depend on the risk of the device, and the firm's compliance with the requirements.	
<b>Conclusion</b>	The findings do <input checked="" type="checkbox"/> do not <input type="checkbox"/> meet the acceptance criteria for this activity.	
<b>Additional Comments</b>		
<b>Activity Champion(s)</b>	Nancy Singer, Special Counsel, HIMA Ken Kopesky, Director of Corporate Compliance and Audit, Medtronic, Inc.	

### Chart Indicating Linkages Between QSIT and the Quality System Regulation

The left column is a breakdown of the QSIT coverage in outline form. The right column is a listing of the sections of 21CFR 820. The right column also identifies the link(s) to the QSIT Outline.

#### QSIT Outline<sup>1</sup>

##### **A Management Controls:**

1. Quality policy
2. Management review
3. Quality audit
4. Quality plan
5. Quality system procedures
6. Organizational structure, responsibility, authority and necessary resources
7. Management representative
8. Suitability and effectiveness of the quality system is reviewed

##### **B Design Controls:**

1. Design control procedures
2. Design plan – assigned responsibilities, interfaces and risk analysis
3. Design inputs
4. Design outputs essential for proper functioning
5. Acceptance criteria
6. Design verification
7. Design validation - user needs and intended uses
8. Design validation – no unresolved discrepancies
9. Software validation
10. Performance of risk analysis
11. Validation with production samples
12. Design change control
13. Design reviews
14. Design Transfer

##### **C Corrective and Preventive Action**

1. Identify appropriate sources of information
2. Information is analyzed
3. Information is complete, accurate and timely
4. Statistical methods and completeness
5. Failure analysis commensurate with the risks
6. Root cause analysis
7. Appropriate actions taken and documented
8. Information disseminated – management review

##### **D Production and Process Controls**

1. Product and Process Control Procedures
2. Controls and monitors
3. Device History Records
4. Nonconformity actions
5. Equipment adjustment, calibration and maintenance
6. Validation study
7. Software validation
8. Personnel qualifications

#### 21 CFR Section 820 Plus Linkages to the QSIT Outline on the Left

- 820.1 Scope - none
- 820.3 Definitions – none
- 820.5 Quality system – A1-A8
- 820.20 Management responsibility – A1-A8
- 820.22 Quality audit – A3
- 820.25 Personnel – A6, D8
- 820.30 Design controls – B1-B14
- 820.40 Document controls – A5, A8, B1, B2, B12, B13, B14, C3, C7, C8, D1, D3, D6-D8
- 820.50 Purchasing controls – B5, B6, B12, C6, C7, D2
- 820.60 Identification – A5, B14, D1, D2
- 820.65 Traceability – A5, B14, D1, D2
- 820.70 Production and process controls – A4, A5, C2 – C7, D1 – D8
- 820.72 Inspection, measuring, and test equipment – A5, C2 – C7, D1 - D8
- 820.75 Process validation – B6 – B8, D5 – D7
- 820.80 Receiving, in-process, and finished device acceptance – A4, A5, C1 – C8, D1 – D5
- 820.86 Acceptance status – A4, D1, D2
- 820.90 Nonconforming product – A2, A4, A5, C1 – C8
- 820.100 Corrective and preventive action – C1 – C8
- 820.120 Device labeling – A5, B3, B7, D1, D2
- 820.130 Device packaging – B3, B7, D1, D2
- 820.140 Handling – A5, D1, D2
- 820.150 Storage – A5, D1, D2
- 820.160 Distribution – A5, D1, D2
- 820.170 Installation – A5, B3, B4, B7, D1, D2
- 820.180 Records, General requirements – A4, A5, B2
- 820.181 Device master record – A4, A5, B4, B5, B14, D1, D2
- 820.184 Device history record – A4, A5, D3
- 820.186 Quality system record – A4, A5, B12, B14, D1 – D8
- 820.198 Complaint files – A5, C1 – C8, D4
- 820.200 Servicing – A4, A5, B7, D1, D2
- 820.250 Statistical techniques – A4, A5, B2, B5, B6, B7, B10, B11, C4, D6

<sup>1</sup> The QSIT Outline numbering does not relate to the numbering in the QSIT Handbook.